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(54) Title: <b>PERITONEAL DIALYSIS SOLUTIONS CONTAINING MALTODEXTRINS AND AMINO ACIDS</b>			
(57) Abstract			
<p>A peritoneal dialysis solution comprising as osmotic agents approximately 2.0 to about 6.0 % (w/v) maltodextrins and approximately 0.25 to about 2.0 % (w/v) amino acids. The peritoneal dialysis solution will also include other components such as sodium, chloride, lactate, bicarbonate, calcium, and magnesium.</p>			

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**WE CLAIM:**

1. A peritoneal dialysis solution comprising as  
osmotic agents:  
5 approximately 2.0 to about 6.0% (w/v) maltodextrins;  
and  
approximately 0.25 to about 2.0% (w/v) amino acids.

2. The peritoneal dialysis solution of Claim 1  
wherein the amino acids comprise both essential and non-  
essential amino acids.

10 3. The peritoneal dialysis solution of Claim 1  
including sodium, chloride, lactate, bicarbonate,  
calcium, and magnesium.

4. The peritoneal dialysis solution of Claim 1  
wherein the solution includes:  
15 120 to about 140 (mEq/L) sodium;  
70 to about 110 (mEq/L) chloride;  
0 to about 45.00 (mEq/L) of lactate;  
0 to about 45.00 (mEq/L) of bicarbonate;  
0 to about 4.00 (mEq/L) of calcium; and  
20 0 to about 4.00 (mEq/L) of magnesium.

5. The peritoneal dialysis solution of Claim 1  
wherein the pH of the solution is approximately 6.0 to  
7.4.

25 6. The peritoneal dialysis solution of Claim 1  
wherein the maltodextrins have the following composition:  
Weight Average Mol. Wt. (Mw) 10,000 - 16,000 daltons  
Number Average Mol. Wt. (Mn) 4,000 - 8,000 daltons  
Polydispersity 1.0 - 4.0  
Fraction > 100,000 daltons NMT 1.0%

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30 Mono, Di, Trisaccharides NMT 5.0%  
Distribution normal  
Alpha (1-4) NLT 90%  
Aluminum (10% solution) <10ppb

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	Aqueous Solubility	NLT 10% (w/v)
	pH (10% solution)	5.0 - 7.0
	Heavy Metals	<5ppm
	DP (Degree of polymerization)	
5	greater than 20	≥ 75%
	DP greater than 50	≥ 50%
	DP greater than 100	≥ 25%

7. The peritoneal dialysis solution of Claim 1  
wherein the maltodextrins are derived from the hydrolysis  
10 of starch.

8. The peritoneal dialysis solution of Claim 1  
wherein the amino acids comprise:

	<u>Amino Acid</u>	<u>Conc. (mg%)</u>
	Leucine	74 - 112
15	Valine	100 - 151
	Threonine	47 - 71
	Isoleucine	61 - 92
	Lysine.HCl	55 - 83
	Histidine	52 - 78
20	Methionine	32 - 48
	Phenylalanine	42 - 62
	Tryptophan	20 - 30
	Alanine	68 - 103
	Proline	43 - 65
25	Arginine	60 - 113
	Glycine	36 - 55
	Serine	48 - 72
	Tyrosine	20 - 35
	Aspartate	55 - 83
30	Glutamate	55 - 83

9. The peritoneal dialysis solution of Claim 1  
wherein the amino acids are chosen so as to have the  
following ratios:

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	<b>Phenylalanine/Tyrosine</b>	<b>1.3 - 3.0</b>
	<b>Essential/Total Amino Acids</b>	<b>0.4 - 0.7</b>
10. The peritoneal dialysis solution of Claim 1 wherein maltodextrins and amino acids comprise the only osmotic agents.		
5		
11. A peritoneal dialysis solution comprising:		
	<b>Maltodextrins (% w/v)</b>	<b>2.0 - 6.0</b>
	<b>Amino Acids (% w/v)</b>	<b>0.25 - 2.0</b>
	<b>Sodium (mEq/L)</b>	<b>120 - 140</b>
10	<b>Chloride (mEq/L)</b>	<b>70 - 110</b>
	<b>Lactate (mEq/L)</b>	<b>0.0 - 45.0</b>
	<b>Bicarbonate (mEq/L)</b>	<b>0.0 - 45.0</b>
	<b>Calcium (mEq/L)</b>	<b>0.0 - 4.0</b>
	<b>Magnesium (mEq/L)</b>	<b>0.0 - 4.0</b>
15	<b>pH</b>	<b>6.0 - 7.4</b>
12. The peritoneal dialysis solution of Claim 11 wherein the maltodextrins are derived from the hydrolysis of starch and have the following composition:		
	<b>Weight Average Mol. Wt. (Mw)</b>	<b>10,000 - 16,000 daltons</b>
20	<b>Number Average Mol. Wt. (Mn)</b>	<b>4,000 - 8,000 daltons</b>
	<b>Polydispersity</b>	<b>1.0 - 4.0</b>
	<b>Fraction &gt; 100,000 daltons</b>	<b>NMT 1.0%</b>
	<b>Mono, Di, Trisaccharides</b>	<b>NMT 5.0%</b>
	<b>Distribution</b>	<b>normal</b>
25	<b>Alpha (1-4)</b>	<b>NLT 90%</b>
	<b>Aluminum (10% solution)</b>	<b>&lt;10ppb</b>
	<b>Aqueous Solubility</b>	<b>NLT 10% (w/v)</b>
	<b>pH (10% solution)</b>	<b>5.0 - 7.0</b>
	<b>Heavy Metals</b>	<b>&lt;5ppm</b>
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30	<b>DP (Degree of polymerization)</b>	
	greater than 20	$\geq 75\%$
	DP greater than 40	$\geq 50\%$
	DP greater than 80	$\geq 25\%$

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13. The peritoneal dialysis solution of Claim 11 wherein the amino acids comprise:

	<u>Amino Acid</u>	<u>Conc. (mg%)</u>
5	Leucine	74 - 112
	Valine	100 - 151
	Threonine	47 - 71
	Isoleucine	61 - 92
	Lysine.HCl	55 - 83
10	Histidine	52 - 78
	Methionine	32 - 48
	Phenylalanine	42 - 62
	Tryptophan	20 - 30
	Alanine	68 - 103
15	Proline	43 - 65
	Arginine	60 - 113
	Glycine	36 - 55
	Serine	48 - 72
	Tyrosine	20 - 35
20	Aspartate	55 - 83
	Glutamate	55 - 83

14. The peritoneal dialysis solution of Claim 11 wherein the amino acids are chosen so as to have the following ratios:

25	Phenylalanine/Tyrosine	1.3 - 3.0
	Essential/Total Amino Acids	0.4 - 0.7

15. The peritoneal dialysis solution of Claim 11 wherein maltodextrins and amino acids comprise the only osmotic agents.

16. A method for providing an osmotic agent for a peritoneal dialysis solution comprising the steps of selecting as the osmotic agent two compositions, one having a molecular weight equal to or greater than 10,000 daltons and comprising approximately 2.0 to about 6.0%

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(w/v) of the composition and a second composition having a molecular weight equal to or less than 300 daltons and comprising approximately .25 to about 2.0% w/v of the composition.

5        17. The method of Claim 16 wherein the osmotic agent includes maltodextrin and amino acids.

10      18. The method of Claim 17 wherein the maltodextrins are derived from the hydrolysis of starch and have the following composition:

10      Weight Average Mol. Wt. (Mw) 10,000 - 16,000 daltons

Number Average Mol. Wt. (Mn) 4,000 - 8,000 daltons

Polydispersity                          1.0 - 4.0

Fraction > 100,000 daltons        NMT 1.0%

Mono, Di, Trisaccharides            NMT 5.0%

15      Distribution                          normal

Alpha (1-4)                            NLT 90%

Aluminum (10% solution)            <10ppb

Aqueous Solubility                    NLT 10% (w/v)

pH (10% solution)                    5.0 - 7.0

20      Heavy Metals                        <5ppm

DP (Degree of polymerization)

greater than 20                        ≥ 75%

DP greater than 50                    ≥ 50%

DP greater than 100                 ≥ 25%

25      19. The method of Claim 17 wherein the amino acids comprise:

<u>Amino Acid</u>	<u>Conc. (mg\$)</u>
Leucine	74 - 112
Valine	100 - 151

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	Methionine	32 - 48
	Phenylalanine	42 - 62
	Tryptophan	20 - 30
	Alanine	68 - 103
5	Proline	43 - 65
	Arginine	60 - 113
	Glycine	36 - 55
	Serine	48 - 72
	Tyrosine	20 - 35
10	Aspartate	55 - 83
	Glutamate	55 - 83

20. A two part peritoneal dialysis solution designed to be mixed prior to infusion into a patient comprising:
- 15        a first part housed in a first structure including approximately 2.0 to about 6.0% (w/v) maltodextrin and a pH of approximately 4.0 to about 5.5;
- a second part housed in a second structure including amino acids; and
- 20        including in either the first or the second structure a sufficient amount of the following ingredients so when the first part and second part are mixed the following is provided: 120 to about 140 (mEq/L) sodium; 70.0 to about 110.00 (mEq/L) chloride; 0.0 to about 5.0 (mEq/L) lactate; 0.0 to about 45.0 (mEq/L) bicarbonate; 0.0 to about 4.0 mEq/L) calcium; and 0.0 to about 4.0 (mEq/L) magnesium.
- 25        21. The two part peritoneal dialysis solution of ~~Claim 20 wherein the first and second structures are two~~ separate chambers of a single container.

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22. The two part peritoneal dialysis solution of  
Claim 20 wherein the pH of a resultant solution,  
comprising a mixture of the first part and the second  
part, is approximately 6.0 to about 7.4.

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